K003733

MAY 2 9 2001

Summary of Safety and Effectiveness Information *Premarket Notification, Section 510(k)*	ORTHOTEC, LLC. NOVEMBER 28, 2000

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. **Device Name:**
   Trade Name: **SCS Closed Screw**
   Common Name(s): pedicle screw, vertebral screw
   Classification Name(s): Pedicle Screw Spinal System (Class II uses)

2. **Establishment Name & Registration Number:**

   Name: **ORTHOTEC, LLC.**
   Number: 2031734

3. **Classification(s):**

   § 888.3050 – Spinal Interlaminal Fixation Orthosis
   § 888.3060 – Spinal Intervertebral Body Fixation Orthosis
   § 888.3070 – Spondylolisthesis Spinal Fixation Device System
   § 888.3070 – Pedicle Screw Spinal System (Class II Uses)

   Device Class: Class II for the requested indications
   Classification Panel: Orthopaedic and Rehabilitation Devices Panel
   Product Code(s): KWP KWQ MNH, MNI respectively

4. **Equivalent Predicate Device:**
   SCS Closed Screws are substantially equivalent to the screws originally cleared in **K983353** (6,7 and 8mm diameter with lengths from 30mm to 80mm) and **K994288** (5mm diameter and 30mm to 80-mm length) as they are manufactured from the same material, have the same dimensional tolerances, the same intended use and have basically the same design.

5. **Device Description:**
   The ***SCS Closed Screws*** are made of titanium and stainless steel per the referenced specifications:

Stainless Steel: 316 LVM	ASTM F138 GR2	ISO 5832-1
Titanium Alloy: Ti6V ELI	ASTM F136-92	ISO 5832-3

The product is manufactured in the same facility as the other components of the SCS Spinal System, following identical manufacturing procedures in full compliance with cGMP regulations.

The ***SCS CLOSED SCREW*** is a closed implant type screw which may be helpful in certain surgical cases when the insertion of the locking clip component to secure the rod to the open implant type screw might be difficult or impossible to perform. The advantage of the ***SCS CLOSED SCREW*** is to enable the surgeon to address the needs of a larger patient population.

The **SCS *CLOSED SCREW*** exists both in stainless steel and titanium in all standard lengths and diameters already cleared for use: 5mm, 6mm, 7mm and 8mm. The product code has an identical coding for product reference in which the number 5-6 or 7 represents the screw diameter, "xx" represents the length of the screw, 2010, represents the reference for stainless steel products and 2T10 represents the reference for titanium products.

Closed Screw	Stainless Steel	Titanium
5mm	2010-F5xx	2T10-F5xx
6mm	2010-F6xx	2T10-F6xx
7mm	2010-F7xx	2T10-F7xx
8mm	2010-F8xx	2T10-F8xx

The new screw only differs from the previously cleared "V" type screw by the fact that the implant is closed. The method of attachment to the rod is identical to all implants of the cleared SCS Spinal System. The screws design, thread design, and other bone attachment characteristics are identical to any "V", "S", "U" type screw already cleared. Rod attachment method is the same as were previously cleared for commercialization. Materials are identical

6. **Applicant Name & Address:**
ORTHOTEC, LLC.
546 Hillgreen Drive
Beverly Hills, CA 90212-4110
Tel: (310) 557-2000 ~ Fax:(310) 843-9500
email: Pbertranou@OrthoTec.net

7. **Company Contact:**
Patrick Bertranou
Regulatory Affairs
ORTHOTEC, LLC.
546 Hillgreen Drive
Beverly Hills, CA 90212-4110
Tel: (310) 557-2000 ~ Fax:(310) 843-9500
email: Pbertranou@OrthoTec.net

8. **Submission Correspondent:**
Patrick Bertranou
ORTHOTEC, LLC.
546 Hillgreen Drive
Beverly Hills, CA 90212-4110
Tel: (310) 557-2000 ~ Fax:(310) 843-9500
email: Pbertranou@OrthoTec.net

9. **Performance Standards:**

United States Food and Drug Administration mandated performance standards for this device do not exist. Various voluntary performance standards are utilized. Voluntary standards utilized include ASTM, Standard Operating Procedures, vendor & process certification and qualification procedures, Quality Systems Regulations, ISO materials standards and ISO 9000 series quality regulations. **ORTHOTEC, LLC.** also meets appropriate general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

10. Special Controls:

Special controls were published in the Federal Register, Vol. 63, No. 143, July 27, 1998 (Orthopedic Devices: Classification and Reclassification of Pedicle Screw Spinal Systems). The following special controls apply to the marketing of this device when used as a posterior pedicle system:

(i) Compliance with material standards,
(ii) Compliance with mechanical testing standard,
(iii) Compliance with biocompatability standard, and
(iv) Compliance with specified labeling requirements.

11. Special Guidance Document Information:
The 510(k) was preapred inaccordance with:
"Guidance for Spinal System 510(k)'s" May 7, 1999.

12. Storage, Packaging & Sterilization Information:

The ***SCS Closed Screw*** is supplied ***"NON-STERILE"*** and must be sterilized prior to use. The recommended sterilization process is high temperature steam autoclave sterilization. The recommended sterilization cycle will produce a Sterility Assurance Level (SAL) of at least 10^{-6}.

The validated cycle is:

Method: Steam
Cycle: Gravity
Temperature: 250°F (121°C)
Exposure Time: 30 minutes

All packages containing implants or instruments should be intact upon receipt. Damaged packaging may indicate the presence of unsafe product. If the package or product is damaged, the product should not be used and should be returned.

Product must be handled, stored and opened in such a way that it is protected from inadvertent damage or contamination. When used, the product must be placed into use following cleaning, sterilization and accepted surgical sterile technique.

13. Summary Comparison Table:

FEATURE	*SCS Closed Screw*	*SCS Closed Screw*	SE?
Indications for Use:	**As a nonpedicle posterior system, the SCS system is indicated for patients with:** degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis), tumors, pseudarthrosis, failed previous fusion; Levels of attachment are the thoracic and lumbar spine, the sacrum and ilium. **As an anterolateral/anterior system the SCS system is indicated for patients with:** degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis), tumors, pseudarthrosis, failed previous fusion; levels of attachment are the thoracic and lumbar spine. **As a posterior pedicle system, the device is indicated for use in skeletally mature patients L3 and below who are:** having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint receiving fusions using autogenous bone graft only, having the device fixed or attached to the lumbar and sacral spine, having the device removed after the development of a solid fusion mass; levels of attachment are the thoracic and lumbar spine, the sacrum and ilium. Posterior pedicle systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment Fracture, dislocation, scoliosis, kyphosis, spinal tumor, failed previous fusion (pseudarthrosis).	SAME	YES
Design:	Cancellous thread pedicle screw, vertebral screws, sacral screws	SAME	YES
Sterile:	Non-sterile	SAME	YES
Sizes:	5.0mm to 8.0 diameter, 30 through 80mm lengths	SAME	YES
Material:	titanium alloy, CP titanium, Stainless Steel	SAME	YES
Manufacturer:	OrthoTec, LLC.	SAME	YES
Product Code:	KWP KWQ MNH MNI	SAME	YES
K - Number:	Pending	**K983353 & K994288**	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 9 2001

Patrick Bertranou, MD
Orthotec, LLC
456 Hillgreen Drive
Beverly Hills, California 90212

Re: K003733
Trade Name: SCS Closed Screw
Regulation Number: 888.3070, 888.3050 and 888.3060
Regulatory Class: II
Product Code: MNH, MNI, KWP and KWQ
Dated: November 29, 2000
Received: December 4, 2000

Dear Dr. Bertranou:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: **K003733**

Device Name: *"Closed Screw" SCS Spinal System Screw*

Indications For Use:

Intended Use(s) of the Device:

When used as a nonpedicle posterior system, the SCS system is indicated for patients with:

degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
spondylolisthesis
fracture
spinal stenosis
deformities (i.e., scoliosis, kyphosis, lordosis)
tumors
pseudarthrosis
failed previous fusion
Levels of attachment are the thoracic and lumbar spine, the sacrum and ilium.

When used as an anterolateral/anterior system the SCS system is indicated for patients with:

degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
spondylolisthesis
fracture
spinal stenosis
deformities (i.e., scoliosis, kyphosis, lordosis)
tumors
pseudarthrosis
failed previous fusion
Levels of attachment are the thoracic and lumbar spine.

When used as a posterior pedicle system, the device is indicated for use in skeletally mature patients L3 and below who are:

having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint
receiving fusions using autogenous bone graft only
having the device fixed or attached to the lumbar and sacral spine
having the device removed after the development of a solid fusion mass.
Levels of attachment are the thoracic and lumbar spine, the sacrum and ilium.

Posterior pedicle systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

degenerative spondylolisthesis with objective evidence of neurologic impairment
fracture
dislocation
scoliosis
kyphosis
spinal tumor
failed previous fusion (pseudarthrosis)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

K003733

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Prescription Use X *(Per 21 CFR 801.109)*

OR

~~*Over-The-Counter Use*~~

510(k) Number K003733

(Optional format 1-2-96)